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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/021,243
Filing Date: December 19, 2001
Appellant(s): SKLAR ET AL.

R. Neil Sudol
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed July 10, 2006 appealing from the Office action mailed April 7, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

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6,132,685	Kercso et al.	10-2000
6,440,645	Yon-Hin et al.	8-2002
471685	Knapp et al.	5-2001
4,853,336	Saros et al.	8-1989
5,679,310	Manns	10-1997
5,846,491	Choperena et al.	12-1998
5,958,148	Holzapfel et al.	9-1999

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

a. Claims 1, 16-18, 21, 24, 27-34, 42-44, 46, 47, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrari, 2,933,293, in view of Kercso et al., 6,132,685.

Ferrari discloses the invention substantially as claimed.

More specifically, as to claims 1 and 34, Ferrari discloses an apparatus (10), (col. 2, line 2) comprising:

first driving means (pump 12 for introducing sample, col. 2, line 7, and see "sample" in figure 1) for driving a plurality of reagent samples into a first fluid flow stream (col. 2, lines 13-14, and lines 58-61);

second driving means (pump 12 for introducing air, col. 2, lines 57-59; and see figure 1) for introducing a separation gas between each of said plurality of reagent samples in said first fluid flow stream;

means for driving a second fluid flow stream (pump 12 for introducing reagent, col. 2, line 7, and see "reagent" in figure 1) comprising a plurality of particles (i.e., the reagent);

a junction device comprising:

a first inlet port (i.e., port near 30 in figure 1, or alternatively one of the ports near 44) for receiving said first fluid flow stream;

a second inlet port (i.e., other port near 30 in figure 1, or alternatively one of the ports near 44) for receiving said second fluid flow stream;

a first reaction zone (at 30, or alternatively, the junction near 44; see col. 2, lines 41 and 42) for forcing mixing between said first fluid flow stream and said second fluid flow stream to thereby form a reaction product stream; and

an outlet port (i.e., port at distal end of 30, or alternatively port distal to the junction near 44) for allowing said reaction product stream to exit said junction device;

a second reaction zone (all of 44 or alternatively, distal-most end of 44) where said plurality of reagent samples and said plurality of particles mix to form a plurality of reaction products, said reaction zone communicating with said outlet port; reaction product driving means (pump, figure 1, lines 7-10, and line 25, and lines 61-62) for driving said reaction product stream through said reaction zone; and means (46) for selectively analyzing said reaction product stream for said reaction products.

However, Ferrari does not specifically teach that the device is small (or microfluidic.) (The Office notes that in the specification on page 7, lines 19-20, Applicant states that '[f]or the purposes of the present invention, the term "microfluidic" refers to the process where contents of two sample lines are mixed in a mixer'. However, since the term microfluidic in the art generally refers to a small device, the Office will interpret microfluidic as claimed in the preamble of claim 1 to refer to a small device.)

Kercso et al. however teach a diagnostic device for analyzing samples that is a microfluidic device and has small channel dimensions (col. 5, lines 11-15). Kercso et al. also refer to the fabrication of the microfluidic device in terms of shape and material (col. 10, lines 45-46 and lines 54-59) and size (col. 5, lines 12-15). Kercso et al. teach that microfluidic devices provide the advantage of testing a large number of sample compounds with a compact sample handling arrangement (col. 2, lines 37-38 and lines 56-58, and col. 4, lines 30-39). It would have been obvious to one of ordinary skill in the

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art at the time the invention was made to form the Ferrari device in the microscale as taught by Kercso et al. because Kercso et al. teach that such a microfluidic device provides the advantage of testing a large number of sample compounds with a compact sample handling arrangement, as would be desirable for convenience. Moreover, Kercso et al. show that the fabrication of small scale diagnostic devices is known by one of ordinary skill in the art. Thus one of ordinary skill in the art would have reasonable expectation of success in scaling down the size of the Ferrari device (the dimensions of which is not mentioned by Ferrari) given that Kercso et al. show that the technology of scaling down diagnostic devices is known.

As to claims 16-18, 21, 24, 29, 30-33, 42-44, 46, 47, 49 and 50, Ferrari discloses the limitations as follows.

As to claim 16, the apparatus further comprises a first tubing (i.e., tubing near "sample" in figure 1) for containing said first fluid flow stream, a second tubing (i.e., tubing near "reagent" in figure 1) for containing said second fluid flow stream and a reaction product tubing (30, or alternatively, tubing near 44, see fig. 1, and col. 2, lines 41-42) for containing said reaction product stream.

As to claim 17, the apparatus includes a unibody flow apparatus (see fig. 1) comprising said first tubing, said second tubing, said reaction product tubing, and said junction device.

As to claims 18, 21 and 24, said first tubing, second tubing, and reaction product tubing comprise high speed multi-sample tubing (col. 2, lines 57-59, disclosing multi-samples in the tubings, the tubing being capable of high speed multi-sampling).

As to claim 29, said separation gas comprises air (col. 2, line 57.)

As to claims 30-33, the apparatus is capable of sampling a plurality of homogenous or heterogeneous samples, and capable of introducing particles comprising biomaterials fluorescently tagged (col. 1, lines 15-20). (Examiner notes that Applicant is claiming a device, and that the limitations in claims 30-33 are directed to intended use, and that the prior art device is capable of performing the intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963.))

As to claim 42, the apparatus further comprises a means (i.e., tubing for primary or secondary processing medium, and pump in figure 1) for injecting a buffer fluid between adjacent reagent samples in said first fluid flow stream. (Examiner notes that the limitation regarding injection of a buffer fluid relates to an intended use, and that the prior art is capable of injecting a buffer fluid through the primary or secondary medium inlets in figure 1.)

As to claim 43, the device is capable of providing a drug as one of said plurality of reagent samples. (Examiner notes that this limitation relates to an intended use, and that the prior art is capable of performing this intended use.)

As to claim 44, said junction device is Y-shaped (see figure 1, above the reference number 44, showing a Y-shape.)

As to claim 46, said junction device is T-shaped (see figure 1, above the reference number 44, showing a sideways "T".)

As to claim 47, a first inlet tube (see near "sample" in fig. 1) and first inlet port (see near "sample" in fig. 1) have the same diameter, a second inlet tube (see near "reagent" in fig. 1) and second inlet port (see near "reagent" in fig. 1) have the same diameter, and an outlet tube (see near distal end of 30, or alternatively distal end of 44) and outlet port (see distal end of 30 or distal end of 44) have the same inner diameter (see fig. 1.)

As to claim 49, said first inlet port and said second inlet port have the same inner diameter and said outlet port has a different inner diameter from said first inlet port and second inlet port (see fig. 1.)

As to claim 50, said outlet port has a larger inner diameter than said first inlet port and said second inlet port (see fig. 1.)

Moreover, as to claims 27 and 28, Ferrari discloses the invention substantially as claimed (see above), except for the first, second and outlet ports having an inner diameter of about 0.005 to about 0.02 inches (claim 27), or 0.01 inches (claim 28).

However, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In this case, Ferrari in view of Kercso et al. teach the general conditions of a claim, including the small scale dimensions (see above), and it would have been obvious to form the tubings, including inlets, having an

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inner diameter as claimed since such diameters provide an optimum or workable range of diameters.

Also, as to claims 35-39, although Ferrari teaches sample vessels (28), (col. 4, line 41), Ferrari does not specifically teach that the number of source wells is 72, 96, 384 or 1536.

Kercso, like Ferrari, discloses a device for analyzing a large number of sample compounds. The samples are contained in standard microtiter plates such as those having 96, 384, 1536 number of wells (col. 3, lines 1-3), and are transferred by autosampling sequentially from the wells into a channel (col. 11, lines 45-50, and col. 15, lines 49-54.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide 96, 384, and 1536 as the number of source vessels, as taught by Kercso, or alternatively, 72 source vessels, in the Ferrari device as well known and conventional numbers of source vessels for autosampling as taught by Kercso, as would be desirable for rapid analysis of a large number of samples.

As to claims 19, 20, 22, 23, 25-26, Ferrari does not disclose that the first tubing comprises PVC and has the specific inner diameter as claimed, or wall thickness as claimed.

Kercso teaches that the channels in the device are formed from PVC (col. 10, line 45-46, line 54, and col. 11, line 2.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the Ferrari channels from

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PVC, as taught by Kercso, as well known and conventional materials used for forming channels for diagnostic bioassays.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form the tubings, including inlets, having an inner diameter or wall thickness as claimed since such diameters and thickness provide an optimum or workable range of diameters, and it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

b. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrari, 2,933,293, in view of Kercso et al., 6,132,685, and further in view of Yon-Hin et al., 6,440,645.

Ferrari in view of Kercso et al. disclose the invention substantially as claimed (see above), except for the angle between any two of said first inlet port and second inlet port and said outlet port being 120 degrees. (While Ferrari disclose Y-shaped inlets, Ferrari is silent as to the exact degrees of the angle formed.)

Yon-Hin et al. disclose an assay device for introducing a sample and reagents, the device having a first inlet port, second inlet port and an outlet port (col. 4, lines 45-49, and col. 5, lines 34-37, and figure 4.) Yon-Hin further discloses an embodiment wherein any two of said first inlet port and second inlet port and said outlet port being about 120 degrees (see figure 4.) It would have been obvious to one of ordinary skill in

the art at the time the invention was made to form the Ferrari first and second inlet port, and the outlet in the configuration as taught by Yon-Hin, as a well known and conventional configuration for providing inlet ports and outlet ports for introduction and mixing of samples and reagents. Moreover, Applicant has not disclosed that the 120 degrees angle solves any stated problem or is for any particular purpose and it appears that an angle that is close to 120 degrees would perform equally well.

c. Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrari, 2,933,293, Kercso et al., 6,132,685, and further in view of Knapp et al., 6,235,685.

Ferrari in view of Kercso et al. disclose the invention substantially as claimed (see above), except for said first inlet port, second inlet port and outlet port each having the same interior diameter.

Knapp disclose a diagnostic assay device having separate channels (1350 and 1355) for samples and reagents, and an outlet port (near mixing zone, 1345), (see figure 13.) Knapp discloses an outlet port and outlet tube having the same interior diameter as the inlet ports for the samples and reagents (see figure 13.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide in the Ferrari device inlet ports for samples and reagents having the same diameter as the outlet port and outlet tube, as taught by Knapp, as a well known and conventional configuration for providing inlet ports and outlet ports for introduction and mixing of samples and reagents. Moreover, Applicant has not

disclosed that the interior diameter being the same solves any stated problem or is for any particular purpose and it appears that having various different interior diameters would perform equally well.

d. Claims 2 and 4-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrari, 2,933,293, Kercso et al., 6,132,685, and further in view of Saros et al., 4,853,336.

Ferrari in view of Kercso et al. disclose the invention substantially as claimed (see above). More specifically, Ferrari teaches an assay device (col. 1, lines 18-20, and col. 2, lines 31-32 and 45) and an inlet for providing fluid samples, air, and reagents (col. 2, lines 9-3, and lines 29-30.) However, Ferrari does not disclose the particular means for introducing fluid samples, air and reagents.

More specifically, as to claims 2 and 4-7, Ferrari does not disclose an autosampler as claimed for introducing fluid samples, air and reagents.

Saros discloses an assay device having means (col. 6, lines 31-32) for mixing fluid samples and a reagent, and detector means (112) for analyzing the mixture. Saros further discloses an autosampler (20, 30 and 60; col. 4, line 37, lines 54, and col. 5, line 1) for introducing fluid samples, air and reagents into the assay device. The autosampler provides an automated means with a controller (10) for aspirating multiple aliquots of fluid samples from fluid sample sources (col.4, lines 50-51) and reagents from reagent sources (col. 4, lines 59-60), and for aspirating air (col. 5, lines 1-2).

As to claim 4, said autosampler includes a probe having a conical tip (62, in fig. 1).

As to claims 5-7, said autosampler includes a hydrophobic probe (i.e., probe is formed from hydrophobic material, col. 5, line 43).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the autosampler as taught by Saros in the Ferrari assay device as the means for introducing fluid samples, air and reagents, as would be desirable for an automated introduction of materials for efficiently carrying out diagnostic assays.

As to claims 8-15, Ferrari discloses that the pump (12) may be of any suitable type pump for pumping samples, processing liquids and air (col. 2, lines 7-10). Moreover, as to claim 10, Ferrari discloses a pump located along said first fluid flow stream between sample/air/reagent inlets and the junction device (see fig. 1.)

However, Ferrari does not give a specific example of a type of pump. More specifically, Ferrari does not teach that the first driving means comprises a first fluid flow stream peristaltic pump (claim 8). (For claim 9, see above rejection regarding multiple-sample tube disclosed by Ferrari.)

Saros however discloses an assay device having means for introducing fluid samples, air and reagents (col. 5, lines 1-2, and col. 6, lines 31-32.) Saros further discloses that the means for pulling all fluids into and through the system is a peristaltic pump (120), (col. 6, lines 52-54.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a peristaltic pump as the specific pump in the Ferrari device as the means for pulling all fluids into and through the system as taught by Saros, as a well known and conventional pump used to move fluids in an assay device. Given the teachings of Ferrari and Saros, one of ordinary skill in the art would have a reasonable expectation of success.

As to claim 11, said second driving means comprises a second fluid flow stream peristaltic pump (i.e., the same peristaltic pump.)

As to claim 12, Ferrari discloses a multi-sample tubing (col. 2, lines 57-59).

As to claims 13-15, it would have been obvious to provide the same peristaltic pump as the first fluid flow stream peristaltic pump, second fluid flow stream peristaltic pump, said reaction product driving means, since both Ferrari and Saros disclose a single pump for moving all fluids and air (see figure 1 in Ferrari, and col. 6, lines 53-54 in Saros.)

e. Claims 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrari, 2,933,293, in view of Kercso et al., 6,132,685, and further in view of Manns, 5,679,310.

Ferrari in view of Kercso et al. disclose the invention substantially as claimed (see above). Although Ferrari teaches sample vessels (28), (col. 4, line 41), Ferrari does not specifically teach wells having conical shape (claim 40), nor well plate mounted in an inverted position (claim 41.)

Manns, like Ferrari, teaches multiwell test plate (20). Manns further teaches that the microtiter plates may be inverted, and conical in shape (col. 6, lines 57-58.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the Ferrari sample vessels into an inverted and/or conical shape, as a well known and conventional shape for microtiter wells as taught by Manns.

f. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrari, 2,933,293, in view of in view of Kercso et al., 6,132,685 and Holzapfel et al., 5,958,148, and further in view of Choperena et al., 5,846,491.

Ferrari in view of Kercso et al. disclose the invention substantially as claimed (see above). More specifically, Ferrari teaches an assay device (col. 1, lines 18-20, and col. 2, lines 31-32 and 45) and an inlet for providing fluid samples, air, and reagents (col. 2, lines 9-3, and lines 29-30.) However, Ferrari does not disclose that the first driving means comprises an autosampler with a probe, and that the microfluidic mixing apparatus includes a means for exposing a probe tip of said probe to a jet of gas to remove liquid from said probe tip. Choperena et al. in view of Holzapfel et al teach these limitations.

Choperena et al. teach an autosampler with a pipetting probe that may be positioned in a well of a reagent pack or sample cup or the like (see abstract, and col. 9, lines 19-21, and lines 43-47 and col. 22, lines 56-62), and wherein the pipetting probe tip can be ultrasonically activated to aid in cleansing and drying of the probe (col. 23, lines 26-29, and col. 9, lines 19-29). Choperena et al. teach that the entire analyzer is

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very compact and that its mechanical simplicity increases the reliability of the analyzer by reducing the number and complexity of moving parts in the analyzer and that the parts of the device are arranged with respect to each other and with respect to the electronics and fluidics of the analyzer so that every assay resource can be accessed by an operator from a single stationary position in front of the analyzer (col. 7, lines 46-56).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an autosampler as taught by Choperena et al. in the Ferrari device because Choperena et al. teach that an autosampler provides the advantage of simplicity and convenience in making every assay resource readily accessible to an operator from a single stationary position in front of an analyzer (such as the Ferrari analyzer). One of ordinary skill in the art would recognize the benefits of providing an autosampler in the Ferrari device in order to more readily provide samples and reagents to the Ferrari diagnostic device as would be desirable for convenience.

Moreover, Holzapfel et al. also teaches the desirability of removing excess water and debris from a probe tip and that the means for drying a probe tip is a device for applying a stream of nitrogen gas to a probe tip to remove excess water or debris (col. 12, lines 34-43.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a means for applying a stream of nitrogen gas to a probe tip, as taught by Holzapfel et al., in the Ferrari in view of Choperena et al. device, because Holzapfel et al. teach that applying a stream of nitrogen gas to a probe tip

removes excess water and debris from a probe tip. One of ordinary skill in the art would recognize the desirability of removing excess water and debris from a probe tip as would be desirable for preventing contamination during an analysis. Moreover, Choperena et al. also teach the desirability of keeping the probe tip clean and dry (see col. 23, lines 26-29, and col. 9, lines 19-29).

Response to Arguments

Appellants' arguments in the brief have been considered but are not persuasive for the following reasons.

Appellants states on page 7 of the brief that the dialyzer of the Ferrari, Jr. device receives air-separated fluid samples from the coil (10) and that aliquots do not mix in the dialyzer with the air-separated samples from the mixing coil (10). Appellants state that, instead, certain molecular or crystalline components cross the permeable barrier from one air-separated fluid stream to join the other air-separated fluid stream. The air-separated fluid stream of secondary processing medium from the tube (28), with changes in ionic components, exits the dialyzer and may be directed to a color development chamber (30), and from the color development chamber, the air-separated fluid stream of secondary processing medium passes to a colorimeter (46) via a supply tube (44). Appellants further state on page 7 of the brief that claim 1 recites a junction device that receives a gas-separated fluid flow sample stream at a first inlet port and a second fluid flow stream at a second inlet port, and that the junction device contains a reaction zone for forcing an initial mixing between the gas-separated first fluid flow

stream and the second fluid flow stream to form a reaction product stream. Appellants argue however that the coil (10), which is the only part explicitly designed to force a mixing of incoming fluid components, is however not a junction device as claimed by Appellants because the coil has a single inlet port rather than two as claimed by Appellants.

This however is not persuasive because the coil (10) is not relied upon by the Office as the claimed junction device. Rather, the Office relies on element (30) as the junction device, wherein the ports leading into element (30) are deemed to be the inlet ports of the junction device and the chamber within element (30) is deemed to be the first reaction zone. Element (30) receives a gas-separated first fluid flow stream through the right inlet to element (30) shown in figure 1 and a second fluid flow stream through the left inlet to element (30) shown in figure 1. Thus the second fluid flow stream from the left inlet mixes with the gas-separated first fluid flow stream from the right inlet. The Office also notes that Appellants are claiming a device and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, element (30) and the inlets to element (30) of the Ferrari, Jr. device are shown to be capable of the intended use by the disclosure of two inlets to element (30), disclosed to be color development chamber, with the gas-separated first fluid flow from either coil (10) or tube (28) and eventually tube (34), (see figure 1 and

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column 2, lines 39-42), and the reagent being provided through tube (32) to the left inlet for producing a color change (see figure 1 and column 2, lines 25-33).

Furthermore, element (44) is alternatively deemed to be the claimed junction device. The gas-separated fluid flow also flows to element (44) because gas-separated sample fluid flow stream, at least from tube (28), enters the dialyzer and exits the dialyzer via outlet tube (42) to heater (36) to coil (40) to conduit (42) and then to tube (44), and eventually to colorimeter (46), (see column 2, lines 39-45, and figure 1). The Office notes that tube (44) is a junction with two inlets shown in figure 1. The right inlet to tube (44) receives the gas-separated sample fluid flow from tube (42) and the left inlet to tube (44) receives fluid medium from chamber (30), (see figure 1.)

Appellants also argue on page 8 of the brief that the dialyzer (18) of the Ferrari, Jr. apparatus has one inlet port (at the top left side of the dialyzer) receiving an air-separated sample stream and another inlet (at the lower left side of the dialyzer) receiving an air-separated stream of secondary processing medium, but that the dialyzer (18) does not permit mixing of the two streams. Appellants state that instead there is a limited migration of ionic components across a semi-permeable membrane. The Office agrees with Appellants' assessment of the dialyzer of the Ferrari, Jr. device. However Appellants' statements are not persuasive against the use of the Ferrari, Jr. reference as prior art because the dialyzer (18) is not relied upon by the Office to be claimed the junction device. Rather, as indicated above, the Office relies upon chamber (30) and the two inlets leading to chamber (30) as the junction device, or alternatively

tube (44) and the two inlets leading to tube (44) as the junction device, as discussed above.

Appellants also argue on page 8 of the brief that the color development chamber (30) of the Ferrari, Jr. device has two inlets ports, but that neither of those ports receives a gas-separated sample stream. Appellants' statement here however is contrary to Appellants' earlier statement on page 7, lines 10-12, that "[t]he air-separated fluid stream of secondary processing medium from the tube (28), with changes in ionic components, exits the dialyzer and may be directed to a color development chamber (30)". Thus, Appellants admit in this earlier statement that the color development chamber (30) receives a gas-separated sample stream. Thus, a port to the color development chamber (30) must receive a gas-separated sample stream. This is shown by the Ferrari, Jr. disclosure in figure 1 and column 2, lines 39 to 42 which shows that gas-separated first fluid flow, at least from tube (28), eventually flow to tube (34) and then to chamber (30) for mixing with reagent from tube (32) for producing a color change, (see figure 1 and column 2, lines 39-42).

Appellants also state on page 8 that the Office contends that the first inlet port and the second inlet port of Appellants' junction device have counterparts in the sample inlet and the reagent inlet of the Ferrari, Jr. pump (12). Appellants state that however those inlets of the Ferrari, Jr. device are inlets to the pump and are necessarily upstream thereof, in contrast to the device of Appellants' claim 1, wherein the junction device and particularly the inlet ports thereof are downstream of the driving means and receive the gas-separated first fluid flow stream and the second fluid flow stream

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therefrom. This argument however is not persuasive because contrary to Appellants' assertion, the Office does *not* contend that the first inlet port and the second inlet port of Appellants' junction device have counterparts in the sample inlet and the reagent inlet of the Ferrari, Jr. pump (12). The Office does *not* rely upon pump (12) to be the claimed junction device, but rather relies upon element (30), which is disclosed by Ferrari, Jr. to be downstream of the driving means, i.e., pump (12). The Office also indicates in the grounds for rejection that element (44) is alternatively deemed to be the claimed junction device. The gas-separated fluid flow also flows to element (44) because gas-separated sample fluid flow stream, at least from tube (28), enters the dialyzer and exits the dialyzer via outlet tube (42) to heater (36) to coil (40) to conduit (42) and then to tube (44), and eventually to colorimeter (46), (see column 2, lines 39-45, and figure 1). Tube (44) is disclosed to be downstream of the driving means, i.e., pump (see figure 1).

Appellants also argue on pages 8-9 that the Office maintains further that the first reaction zone and the second reaction zone of Appellant's' device correspond to reference numerals (30) and (44) in the Ferrari, Jr. reference. Appellants maintain that however according to Appellants' claim 1, the first reaction zone is the situs of initial mixing between the gas-separated first fluid flow stream and the second fluid flow stream to thereby form a reaction product. Appellants assert that such mixing cannot occur at the locations of reference numeral (30) or (44) in the Ferrari, Jr. mixing circuit because the gas-separated sample fluid flow stream from the upper part of the Ferrari, Jr. circuit does not flow to those locations. Appellants maintain that the gas-separated sample fluid flow stream from the upper part of the Ferrari circuit follows a separate path

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from that of the reagent flow stream and does not mix therewith. Instead, the gas-separated sample fluid flow stream from the upper part of the Ferrari, Jr. circuit flows into the upper portion of the dialyzer (18) at the left side thereof and flows out of the dialyzer at the upper right port thereof. Appellants assert that gas-separated sample fluid flow stream from the upper part of the Ferrari, Jr. circuit never flows to locations (30) and (44) in the Ferrari, Jr. circuit. This however is not persuasive because gas-separated sample fluid flow stream flow from at least the lower part of the circuit, i.e., from the tube (28), to chamber (30). As admitted from Appellants' statement earlier at the bottom of page 7, lines 10-12, "the air-separated fluid stream of secondary processing medium from the tube (28), with changes in ionic components, exits the dialyzer and may be directed to a color development chamber (30)". Thus, Appellants admit that gas-separated sample fluid flow stream flow to chamber (30). Furthermore, reagents for producing a change in color are provided from tube (32) for mixing with liquid which flows to chamber (30) through tube (34), (see column 2, lines 25-33, and see figure 1). As to element (44), which is alternatively deemed to be the claimed junction device, gas-separated fluid flow also flows to element (44) because gas-separated sample fluid flow stream exits the dialyzer, as admitted by Appellants, and flow through valve (38) to outlet tube (42) to heater (36) to coil (40) to conduit (42) and then to tube (44), and eventually to colorimeter (46), (see column 2, lines 39-45, and figure 1). The Office notes that tube (44) is a junction with two inlets shown in figure 1, with the right inlet to tube (44) receiving the gas-separated sample fluid flow from tube

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(42), and the left inlet to tube (44) receiving fluid medium from chamber (30), (see figure 1.)

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

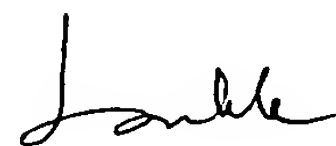
Handwritten signature of Ann Lam, dated 7/25/06.

Ann Lam

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JANET L. ANDRES
SUPERVISORY PATENT EXAMINER